K132221

JAN 31 2014

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

1. **Submitter's Identification:**
   Shandong Haoyu Medical Products Co., Ltd.
   No.8, Nanhuan Road, Shaozhuang Industry Park
   Qingzhou, Shandong, China

   Contact Person:
   Shao Le
   Phone Number: 011-86-536-3840824

   Date summary prepared: Jan 22, 2014

2. **Name of the Device:**
   Powder Free Vinyl Patient Examination Gloves

3. **Predicate Device Information:**
   Shijiazhuang Star Plastics Co., Ltd.
   Powder Free Vinyl Patient Examination Gloves, Clear (K100699)

   Tangshan Zhonghong Pulin Food Products Co., Ltd.
   Class I vinyl patient examination gloves, powder-free (K022091)

4. **Device Description:**
   A Powder-Free Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

5. **Standard Description:**
   Our Powder-Free Vinyl Patient Examination Gloves do not contain any UPS powder according to the results of testing conducted on the gloves. The residual powder testing is conducted per standards of ASTM D-6124-06, which demonstrates that the powder free glove is less than 2mg/pc. Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Glove, 80LYZ, and meets all requirement of ASTM Standard D5250-06.

6. **Intended Use:**
   A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

7. **Comparison to Predicate Devices on Indication for Use:**
Our Powder Free Vinyl Patient Examination Gloves are substantially equivalent in safety and effectiveness to Tangshan Zhonghong Pulin Food Products Co., Ltd. (K022091) and Shijiazhuang Star Plastics Co., Ltd. (K100699) Powder-Free Vinyl Patient Examination Gloves.

8. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**
The standards used for Shandong Haoyu Medical Products. Co. Ltd. gloves product are based on ASTM-D-6319 and ASTM D-5250. All testing meets requirements for physical and dimensions testing conducted on gloves. Inspection level S-2, AQL 2.5.

The FDA 1000 ml Water Fill Test based on ASTM-D5151-06 was also conducted samplings of AQL 2.5 inspection level G-1, meeting these requirements. Primary Skin Irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

9. **Sterilization**
There is no specific device for non-sterile examination gloves. Hand hygiene by rubbing with an alcohol-based hand rub or by washing with soup and water should be performed when appropriate.

10. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

11. **Conclusions:**
Our Powder-Free Vinyl Patient Examination Gloves conforms fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references. and. meets pinhole FDA requirements, biocompatibility requirements and labeling claims. and are substantially equivalent in all technological characteristics. including tensile strength. ultimate elongations size. thickness. residual powder and pinhole to predicate devices. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K022091)	Predicate Device (K100699)
Description	Powder Free Vinyl Patient Examination Gloves	Class I vinyl patient examination gloves, powder-free (Tangshan Zhonghong Pulin Food Products Co., Ltd)	Powder Free Vinyl Patient Examination Gloves, Clear (Shijiazhuang Star Plastic Co., Ltd)
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Substantially equivalent	Substantially equivalent
Basic Design	A garment covering the hand and wrist area. Have separate openings for each finger and the thumb.	Substantially equivalent	Substantially equivalent
Materials Used	Poly Vinyl Chloride	Same	Same
Single Use	Yes	Yes	Yes
Size	S,M,L,XL	S,M,L,XL	Information Unavailable
Sterile	Not sterile	Not sterile	Not sterile
Dimension	Meets ASTM D5150-06	Meets ASTM D5150-06	Meets ASTM D5150-06
Physical Property	Meets ASTM D5150-06	Meets ASTM D5150-06	Meets ASTM D5150-06
Free of Pinhole	Meets ASTM D5151-06	Meets ASTM D5151-06	Meets 21 CFR 800.20
Residue Powder	Meets ASTM D6124-06	Meets ASTM D6124-06	Meets ASTM D6124-06
Primary Skin Irritation	Not an irritant	Not an irritant	Not an irritant
Dermal Sensitization	Not a sensitizer	Not a sensitizer	Not a sensitizer
Summary of comparison	Our Powder-Free Vinyl Patient Examination Gloves (subject device) and Tangshan Zhonghong Pulin Food Products Co., Ltd Class I vinyl patient examination gloves, powder-free (K022091) (predicate device), and Shijiazhuang Star Plastic Co., Ltd Powder Free Vinyl Patient Examination Gloves, Clear (K100699) (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

Shandong Haoyu Company Medical Products Company, Limited
C/O Mr. Ray Zhou
Official Correspondent
Basic Medical Industries, Incorporated
12390 East End Avenue
Chino, CA 91710

Re: K132221
Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: December 30, 2013
Received: January 2, 2014

Dear Mr. Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

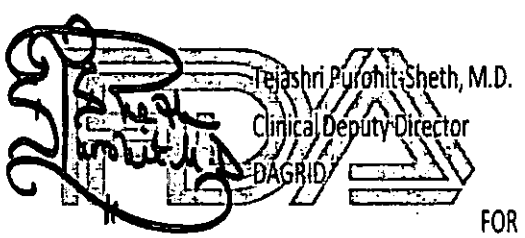
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132221

Device Name
Powder Free Vinyl Patient Examination Gloves

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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